

<b>Case Number:</b>	CM15-0006804		
<b>Date Assigned:</b>	01/26/2015	<b>Date of Injury:</b>	03/29/2011
<b>Decision Date:</b>	03/13/2015	<b>UR Denial Date:</b>	01/05/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/13/2015

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 47 year old male, who sustained an industrial injury on 3/29/2011. The diagnoses have included low back pain, neck pain, headache, constipation, Gastroesophageal Reflux Disease (GERD), and insomnia. Electromyogram study of lower extremity completed 6/11/2012 suggestive of left S1 radiculopathy. Magnetic Resonance Imaging (MRI) of cervical spine 2/23/2013, significant for cervical fusion C5-6, multilevel cervical spondylosis and bilateral foraminal stenosis. Lumbar Magnetic Resonance Imaging (MRI) 11/17/11, positive for multilevel stenosis and nerve impingement. Treatment to date has included medications, home exercise, therapeutic lumbar epidural steroid injection, and was enrolled into a functional restoration program. Currently December 3, 2014, the IW complains of persistent low back pain radiating to left lower extremity, and also neck pain radiating to right shoulder. Pain was rated 10/10 VAS without medications, 4/10 with medications. Physical examination documented 5/5 bilateral strength and normal Range of Motion (ROM) of lower extremities. Plan of care included continuation of previously prescribed medications. Current diagnoses listed included cervical post-laminectomy syndrome, sciatica, disorders of the sacrum and lumbar spinal stenosis. Plan of care included continuation of medications, massage therapy, and possible multi-level spinal fusion that was documented to have been refused. On 1/5/2015 Utilization Review non-certified Miralax powder packets 17g #30, Topiramate-Topamax 25mg #60, Trazodone 50mg #90, Tramadol 150mg #60, Docusate Sodium 100mg #60, Diclofenac Sodium 1/5% 60g and Orphenadrine-Norflex ER 100mg #90, noting the documentation did not support regulation guidelines were met. The MTUS and ODG Guidelines were cited. On 1/13/2015, the injured

worker submitted an application for IMR for review of Miralax powder packets 17g #30, Topiramate-Topamax 25mg #60, Trazadone 50mg #90, Tramadol 150mg #60, Docusate Sodium 100mg #60, Diclofenac Sodium 1/5% 60g and Orphenadrine-Norflex ER 100mg #90, all from DOS: 12/3/2014.

### **IMR ISSUES, DECISIONS AND RATIONALES**

The Final Determination was based on decisions for the disputed items/services set forth below:

#### **Topiramate-Topamax 25mg #60: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs), pages 16-21.

**Decision rationale:** Per MTUS Guidelines, Topamax is recommended for limited use in select chronic pain patients as a fourth- or fifth-line agent and indication for initiation is upon failure of multiple other modalities such as different NSAIDs, aerobic exercise, specific stretching exercise, strengthening exercise, tricyclic anti-depressants, distractants, and manipulation. This has not been documented in this case nor has continued use demonstrated any specific functional benefit on submitted reports from treatment previously rendered. There is no failed conservative first-line treatment modality, documented ADL limitations of neuropathic origin, or acute flare-up or red-flag conditions to support for its use. The Topiramate-Topamax 25mg #60 is not medically necessary and appropriate.

#### **Trazadone 50mg: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-depressants for Treatment of Chronic Persistent Pain, Page 13-16.

**Decision rationale:** MTUS Medical Treatment Guidelines specifically do not recommend for Trazadone, a Selective Serotonin Uptake Inhibitor. Per Guidelines, Trazadone is one of the most commonly prescribed agents for insomnia. Side effects of this drug include nausea, dry mouth, constipation, drowsiness, and headache. Improvements in sleep onset may be offset by negative next-day effects such as ease of awakening. Tolerance may develop and rebound insomnia has been found after discontinuation of sedating antidepressants (e.g., amitriptyline, trazadone, mirtazapine), but may be an option in patients with coexisting depression that have not been identified here. Submitted reports have not adequately demonstrated functional improvement from treatment already rendered as the patient continues to treat for chronic symptoms. Trazadone 50mg is not medically necessary and appropriate.

#### **Tramadol 150mg, #60: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, page(s) 74-96.

**Decision rationale:** Per the MTUS Guidelines cited, opioid use in the setting of chronic, non-malignant, or neuropathic pain is controversial. Patients on opioids should be routinely monitored for signs of impairment and use of opioids in patients with chronic pain should be reserved for those with improved functional outcomes attributable to their use, in the context of an overall approach to pain management that also includes non-opioid analgesics, adjuvant therapies, psychological support, and active treatments (e.g. exercise). Submitted documents show no evidence that the treating physician is prescribing opioids in accordance to change in pain relief, functional goals with demonstrated improvement in daily activities, decreased in medical utilization or change in functional status. There is no evidence presented of random drug testing or utilization of pain contract to adequately monitor for narcotic safety, efficacy, and compliance. The MTUS provides requirements of the treating physician to assess and document for functional improvement with treatment intervention and maintenance of function that would otherwise deteriorate if not supported. From the submitted reports, there is no demonstrated evidence of specific functional benefit derived from the continuing use of opioids with persistent severe pain for this chronic injury without acute flare, new injury, or progressive deterioration. The Tramadol 150mg, #60 is not medically necessary and appropriate.

**Docusate Sodium 100mg, #60: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioid-Initiating Therapy and Long-term users of Opioids, pages 77 & 88.

**Decision rationale:** Docusate Sodium is a medication that is often provided for constipation, a common side effect with opioid medications. The patient continues to treat for chronic symptoms for this chronic injury; however, although it was noted the patient has symptoms of constipation, there was no clinical findings related to GI side effects. Although chronic opioid use is not supported, Docusate Sodium (Colace) a medication that is often provided for constipation, a common side effect with opioid medications may be provided for short-term relief as long-term opioid use is supported; however, submitted documents have not adequately addressed or demonstrated the indication of necessity for this medication with opiates not indicated for this chronic injury. The Docusate Sodium 100mg, #60 is not medically necessary and appropriate.

**Diclofenac Sodium 1.5% 60g: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs), page(s) 22.

**Decision rationale:** Per Guidelines, The efficacy in clinical trials for this treatment modality has been inconsistent and no long-term studies have shown their effectiveness or safety. Topical Diclofenac is recommended for osteoarthritis after failure of an oral NSAID or contraindications to oral NSAIDs after consideration of increase risk profile of severe hepatic reactions including liver necrosis, jaundice, fulminant hepatitis, and liver failure (FDA, 2009), but has not been demonstrated here. The efficacy in clinical trials for topical NSAIDs has been inconsistent and most studies are small and short duration. Topical NSAIDs are not supported beyond trial of 2 weeks as effectiveness is diminished similar to placebo effect. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety beyond 2 weeks especially for this chronic injury. There is no documented functional benefit from treatment already rendered. The Diclofenac Sodium 1.5% 60g is not medically necessary and appropriate.

**Orphenadrine-Norflex ER 100mg, #90:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants, pg 128.

**Decision rationale:** Guidelines do not recommend long-term use of this muscle relaxant for this chronic injury. Additionally, the efficacy in clinical trials has been inconsistent and most studies are small and of short duration. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. Submitted reports have not adequately demonstrated the indication or medical need for this treatment and there is no report of significant clinical findings, acute flare-up or new injury to support for its long-term use. There is no report of functional improvement resulting from its previous treatment to support further use as the patient remains functionally unchanged. The Orphenadrine-Norflex ER 100mg, #90 is not medically necessary and appropriate.

**Miralax powder Packets 17g, #30:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines, pg 77Initiating Therapy.

**Decision rationale:** Miralax (Polyethelyn Glycol) is used in the treatment of occasional constipation (irregularity). This product should be used for 7 days or less as excessive use can upset the body's chemical balance and lead to dependence on laxatives. Submitted reports have not adequately documented indication for the medication's continued use when it was noted the patient had no benefit pending GI motility clinic evaluation. Additionally, there is no mention of constipation as a side effect from any opiates use as none appear to have been prescribed per medication list. The Miralax powder Packets 17g, #30 is not medically necessary and appropriate.